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To: BHINER@orahq.ora.fda.gov

Subject: I OPPOSE DRAFT M.O.U. Docket No. 98N-1265 0641 '99 JUN -7 A9:50

Elizabeth Hiner, R.Ph.
Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

I OPPOSE DRAFT M.O.U. being proposed by the FDA.

I have been using compounded pharmacy micronized progesterone and micronized testosterone as part of my regimen of postmenopausal HRT. The items and format are not available in regular pharmacies. the micronized progesterone is a slow-release tab not the usual progesterone in oil, the micronized T is just not available otherwise. These items are a mainstay of my HRT which has facilitated my compliance.

The amounts I use are usual and appropriate for HRT and prescribed by my NYU Ob-gyn Associates gynecologist.

In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

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